A Protocol Lifecycle Tracking Tool for Clinical Research

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Abstract

The High Performance Computing and Informatics Office (HPCIO) of the Center for Information Technology (CIT) is working with the caBIG® Clinical Trial Management System (CTMS) Workspace to develop a Protocol Lifecycle Tracking (PLT) tool that addresses a need across all National Cancer Institute (NCI) cancer centers to improve the tracking and management of clinical trials. PLT has been designed to assist researchers in tracking protocol status throughout a protocol's lifecycle, starting at concept development and continuing with submissions and publications through to the end of the cycle [1]. With real-time protocol status information in hand, those who are responsible for the conduct of a trial and the overall success of a clinical trials program can see the progress of all protocols. Center directors, researchers, and trial coordinators will be able to identify bottlenecks and latencies and take appropriate corrective actions to streamline the process.

Problem Statement

Current protocol tracking systems are often organization-specific and generally do not provide status of a protocol that covers its entire lifecycle. The following are some of the challenges faced by clinical research organizations [2]:

1. Investigators and administrative staff are not able to view and monitor protocol status across different research centers in real-time for identifying delays in the progress of trials.

2. The protocol lifecycle workflows vary between different participating centers, which makes it even more difficult for the coordinating center to track and report their status.

3. The workflow is often opaque, containing potential redundancies and a lack of adherence to protocol milestones among research entities.

4. There is a lack of standards and tools for creating, sharing and reusing protocol lifecycle data elements and workflows across participating research centers.
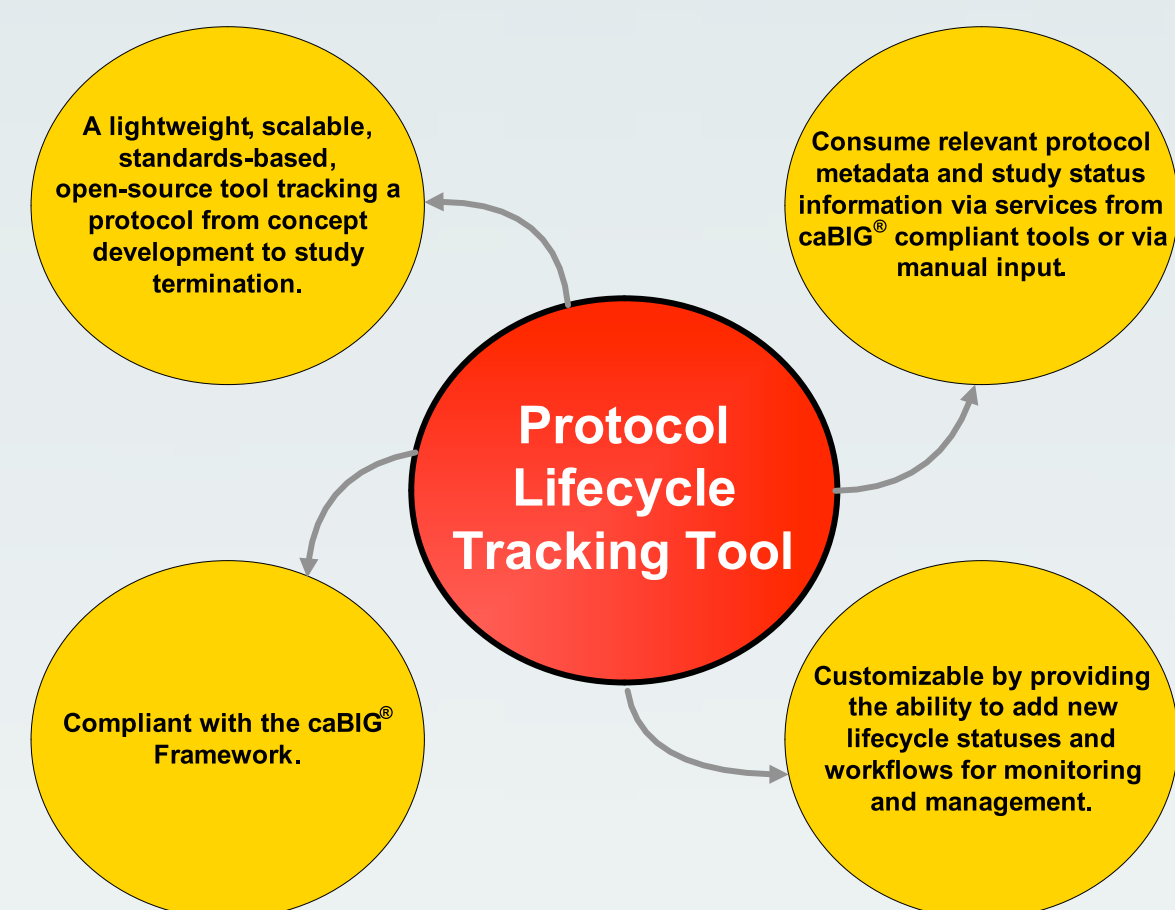
Problem Solution

Figure 1. Highlights of the Protocol Lifecycle Tracking Tool

PLT as highlighted in Figure 1 provides the following functionality:

✓ A dashboard for researchers to visualize overall protocol progress as well as drill-down to specific task status

✓ A workflow builder that allows centers to define custom protocol workflows and tailor standard workflows to meet the specific needs of each center

✓ Ability to upload documents and publications relevant to the lifecycle of the study

✓ A faceted navigation to let users search and browse protocol and status information by selecting from multi-faceted criteria

✓ Use COPPA core services [3] to access real-time Protocol, Person and Organization information from the caGRID for centers to use in tracking their studies

✓ Web services on the caGRID to share protocol, status and workflow definition between coordinating and participating centers.

Protocol Status Dashboard

The PLT functions as a portal for accessing real-time, on-demand protocol status information for those with authorized access privileges. The PLT dashboard provides a grouped/individual list of protocols along with its overall status of all activities for each protocol as shown in Figure 2a. From the list of protocols, users can drill down to the protocol workflow and view the status of the protocol milestones. In addition, users can also take action on completing or approving a milestone. The filtered view of protocols, as shown in Figure 2b, allows users to search information using faceted navigation along several dimensions in any combination.

Figure 2a. Grouped list of protocols, each with an overall activity status. The red flag in the status column indicates impediments to the completion of one or more milestones.

Figure 2b. List of protocols in a filtered view. Users can explore data based on the facets on the side bars.

Workflow Design and Standardization

Administrators from the protocol coordinating site can use PLT to design protocol workflows that can be used by all the participating sites. The current process is a three-level-deep workflow which consists of **state**, **stage**, and **milestone**. User can create a workflow by adding *stages* to a *state* and adding the associated *milestones* to each *stage* as shown in Figure 3. PLT uses an AJAX-based user interface for the workflow designer. Users can easily add, modify and re-order the milestones. Once a workflow is designed and evolved through the complex clinical trials process, it can be standardized for new protocols through a standards body for approval. Thus PLT can serve as a means to help the standardization of workflows and milestones which will improve the efficiency of tracking and reporting protocol status for conducting future clinical trials.
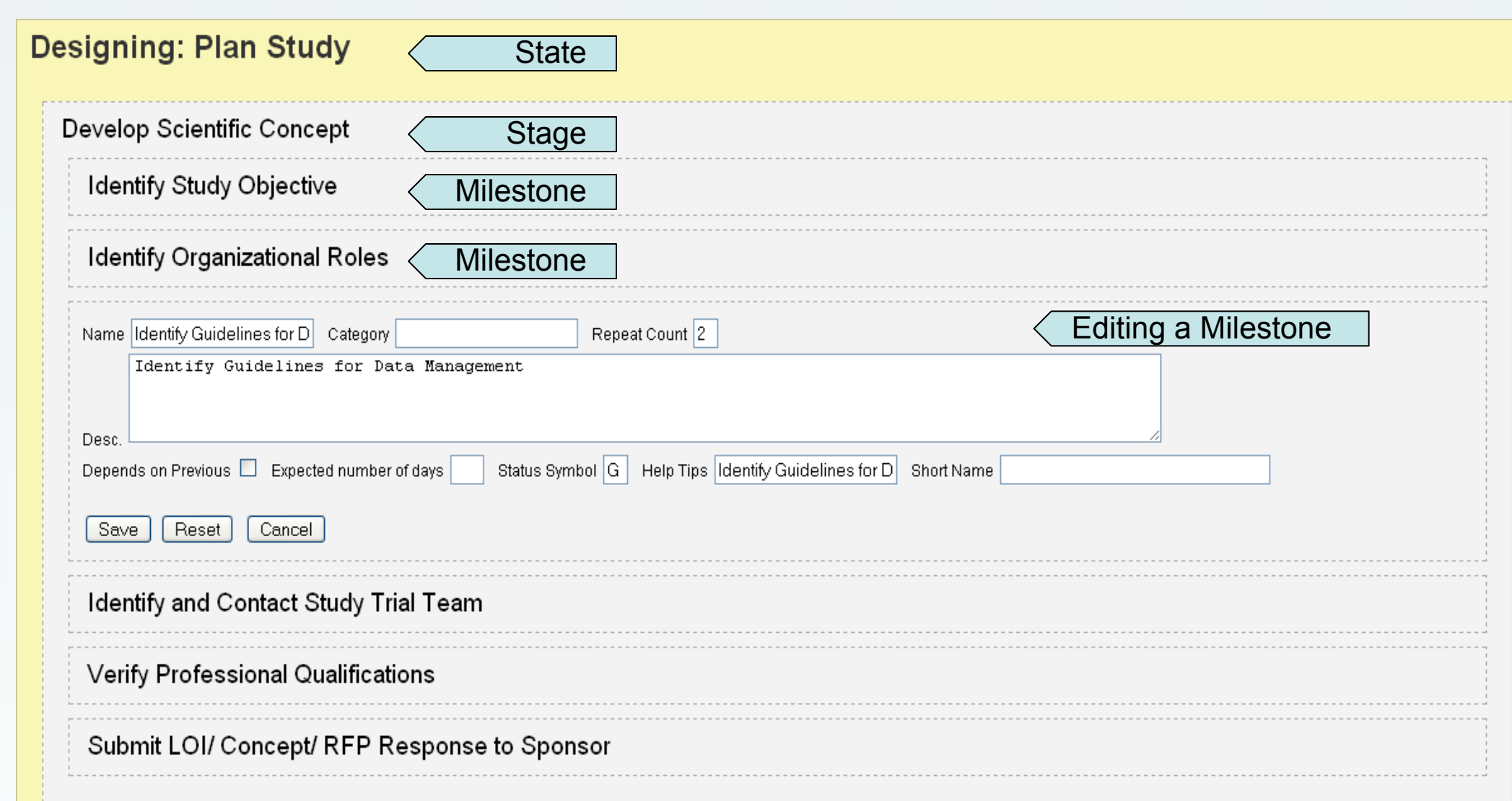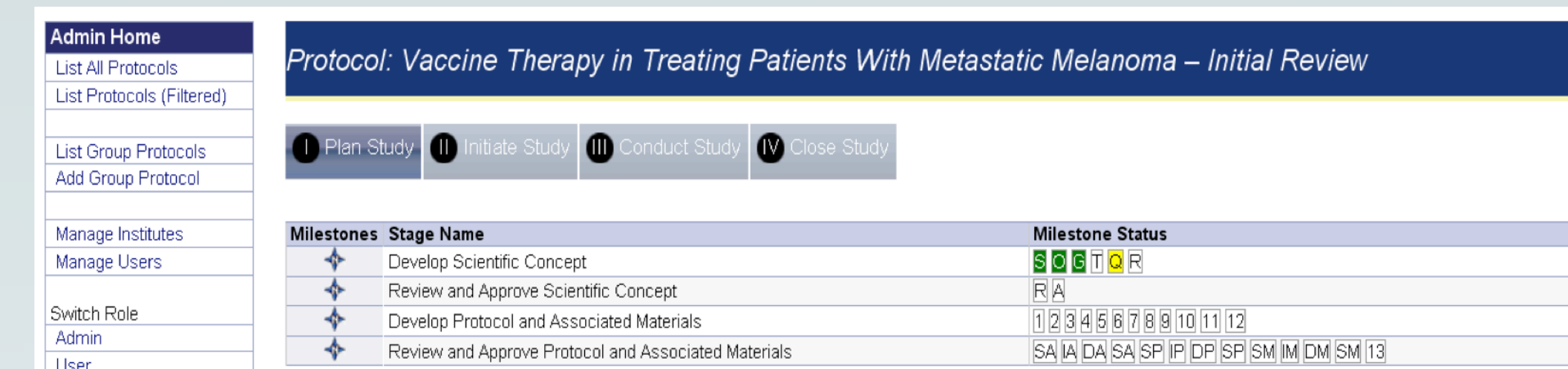

Figure 3. Workflow Design Example: A *Plan Study* state consists of a *Develop Scientific Concept* stage with multiple milestones such as *Identify Study Objective*, etc.
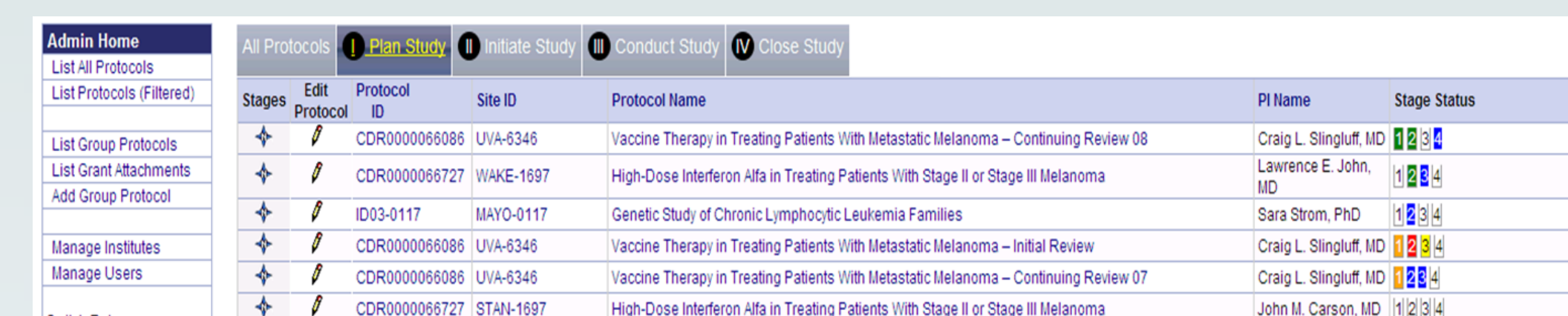
Milestones Status

Milestones are the most basic building blocks in the protocol lifecycle. They are the essential steps for the completion of a specific task (stage) within a well-defined state (workflow) of a protocol's lifecycle. Users with appropriate credentials can create these necessary steps as described in the *Workflow Design and Standardization* section or drill down to the milestone level to manage the protocol's progress during the lifecycle of a study. There are several optional properties available in a milestone: 1) a milestone can be preset with "Expected Number of Days" for completion. When a milestone has gone past it's due date, the status "box" for that milestone will turn to red as an alert for administrator to take appropriate actions; 2) when milestones are required to execute in a sequence, "Depends on Previous" will require the completion of one milestone before the next one can start; 3) an administrator can use alphanumeric characters as a status symbol to represent the name of the milestone, such as "S" for the "Identify Study Objective." The status symbols of a sequence of milestones within a stage are displayed in a row of boxes as shown in Figure 4a. These boxes in term are rolled up into stage when viewing statuses at the protocol level as shown in Figure 4b.

Figure 4a. Status of milestones for a stage is displayed as a row of color-coded boxes. There are four stages along with their milestones and milestone status shown in the "Plan Study" state.

Figure 4b. Milestone statuses are rolled up into stages and displayed as a row of color-coded boxes for each protocol.

Next Step : caGRID Integration

caGRID integration involves standardizing the status and workflow data models by harmonizing with the BRIDG [4] data model and the BAM [5] to allow sharing of information across caGRID. Currently the Protocol, Person and Organization classes are created and stored locally in the application. Next steps involve integrating with the COPPA web services from caGRID to enable the application to consume Protocol, Person and Organization information from caGRID through web service calls. In addition, PLT would provide status and workflow information to caGRID so that this information can be shared across the coordinating and the participating sites. Using the PLT web services from the caGRID, other applications with the proper permissions can consume protocol status information.

References

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Acknowledgement